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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. SERIAL NUMBER FILING DATE LADNER7CUSA R 10/13/93 LADNER 08/133,031 LUKTON, EXAMINER 18M2/0817 PAPER NUMBER **ART UNIT** BROWDY & NEIMARK 419 SEVENTH STREET, N.W. WASHINGTON, DC 20004 1811 08/17/94 DATE MAILED: This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS Responsive to communication filed or A shortened statutory period for response to this action is set to expire month(s), days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133 Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION: 1. Notice of References Cited by Examiner, PTO-892. Notice of Draftsman's Patent Drawing Review, PTO-948. Notice of Art Cited by Applicant, PTO-1449. Notice of Informal Patent Application, PTQ-15 5. Information on How to Effect Drawing Changes, PTO-1474... 1. D Claims are pending in the application. are withdrawn from consideration. Of the above, claim: 3. Claims are allowed. 4. Claims are objected to. are subject to restriction or election requirement. 7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes. 8. Formal drawings are required in response to this Office action. 9. The corrected or substitute drawings have been received on Under 37 C.F.R. 1.84 these drawings are ☐acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948). \_. has (have) been approved by the 10. The proposed additional or substitute sheet(s) of drawings, filed on examiner;  $\Box$  disapproved by the examiner (see explanation). 11. The proposed drawing correction, filed , has been approved; disapproved (see explanation). 12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has Deen received D not been received Deen filed in parent application, serial no. \_ \_\_; filed on \_ 13. Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. 14. Other

Serial No. 133,031 Art Unit 1811

This application contains sequence disclosures that are encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures. For example, the data of tables 13 and 220 would be subject to the CRF listing requirement.

Applicant is given the time period set in this letter within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period.

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In the preliminary amendment (paper No. 7), applicant requested the cancellation of claims 4-16, 12 and 13. This is regarded as an error, i.e., claims 4-6, 12 and 13 have been cancelled.

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Serial No. 133,031 Art Unit 1811

Restriction to one of the following inventions is required under 35 U.S.C. §121:

- I. Claims 1, 3, 14, 16, 17, 19, 20, 22-24 and 28, drawn to inhibitors of human neutrophil elastase derived from BPTI or ITI-D1, classified in e.g., 514/12.
- II. Claims 2, 15, 18, 21, drawn to inhibitors of cathepsin G classified in e.g., 530/324.
- III. Claims 7-11, 25-27, drawn to tri- and tetrapeptides and cyclic tetrapeptides, classified in e.g., 514/18.

The inventions are distinct, each from the other. Groups I and II are distinct because different enzymes are involved. The sequences and properties of the two enzymes differ, their physiological roles differ, and more important, inhibitors of one enzyme cannot be assumed to be effective against the other. Different searches would also be required.

Group III claims differ from those of Groups I and II in part because Group III claims are drawn to tri- and tetrapeptides. Group I and II claims are drawn to much larger peptides having at least 50 amino acids. Clearly, the chemical, physical and biological properties will differ between the two classes of peptides. The patent classification system also recognizes clear differences between tetrapeptides and peptides with more than 25 amino acids.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of

their divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

A telephone call was made to Iver Cooper on 8/11/94 to request an oral election to the above restriction requirement, but did not result in an election being made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ROBERT J. HILL, JR.
SUPERVISORY PATENT EXAMINER
GROUP 1800